



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

D1363 B

PHILADELPHIA DISTRICT

WARNING LETTER

800 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

98-PHI-10

January 22, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jyoti Gupta, President
Gourmail, Inc.
800 Chester Pike
Sharon Hill, PA 19079

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>1/23/98</u>
Reviewed by: <u>Wm W. Krupke</u>	

Dear Ms. Gupta:

An inspection of your Low Acid Food processing plant was conducted by Investigator Joseph Dougherty of the Food and Drug Administration December 10-12, 1997. At the conclusion of the inspection you were presented with a form FDA-483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR), Section 113. This section covers the Good Manufacturing Practices for Low Acid Canned Foods (LACF). By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Food Drug and Cosmetic Act (the Act).

Specifically, our investigator found that:

1. You have not measured and recorded critical factors as specified in the scheduled process. Critical factors specified in the scheduled process shall be measured and recorded on the processing record at intervals of sufficient frequency to ensure that the factors are within the limits specified in the scheduled process. [21 CFR 113.40(a)(13)] For example:

- Bean Soup with Vegetables (Sambar): Carrot thickness and fill weight.
- Soup with Dumplings (Karhi): Fritter size and number per can.

2. On at least three occasions temperature recorders showed higher readings than the mercury-in-glass thermometer while processing low acid canned foods. Also, you have no method of preventing unauthorized changes to the temperature recorder. The temperature chart shall be adjusted to agree as nearly as possible with the mercury in glass thermometer, but should not read higher [21 CFR 113.40(a)(2)].

Jyoti Gupta, President

Page 2

3. You have failed to record and maintain processing and production records as follows:

- a. Recording the time steam was turned off when processing low acid canned foods in your still retorts. Recording vent temperature when processing low acid canned foods in your still retorts. [21 CFR 113.100 (a)(1)].
- b. Retort operators or a designated person did not sign or initial entries made on the retort processing form. Processing records were not reviewed for completeness and to ensure that the product received an adequate cook by a qualified member of management [21 CFR 113.100(b)].

4. You have not established a deviation file to document actions taken when a food product is not processed according to the scheduled process for that food product. For example, on 12/9/97 Curry Sauce (Rogan Josh) was processed with an initial temperature of 76°F when the scheduled process called for 90°F [21 CFR 113.89].

We also noted the following items: The mercury-in-glass thermometers used in your retorts were not recalibrated within a year of the previous test. Such thermometers shall be tested upon installation and at least once year thereafter. Also, you have no written recall plan as required by regulation.

In addition to the GMP deficiencies discussed above, our investigator also found the following serious deficiencies.

1. You did not adhere to the filed process for processing low acid foods as follows:

Product	Date	Scheduled IT	Actual IT
Soup w/Dumplings	10/23/97	90°F	80°F
Spinach Greens	10/23/97	90°F	85°F
Bean Soup	10/23/97	90°F	88°F

Although your processing authority certified these lots as meeting minimum health requirements, you should review your filed processes with your processing authority. The schedules filed should be those used to process your products. If you change the previously filed scheduled process, the changes shall be substantiated by a process authority and filed with the Agency. [21 CFR 108.35(c)(2)(ii)]

2. You failed to list critical factors on the scheduled process that are specified by your processing authority. For example:

- o Chick Peas/Potatoes - Potato thickness and maximum fill weight
- o Peas and Cheese - Cheese thickness and fill weight

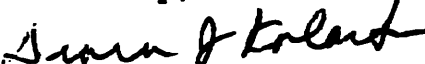
Jyoti Gupta, President
Page 3

A commercial processor shall provide the Food And Drug Administration information as to the scheduled process including critical control factors affecting heat penetration. [21 CFR 108.35(c)(2)]

We acknowledge your promise to Investigator Dougherty that you will correct all deficiencies observed. You should take prompt action to correct these deficiencies. Failure to correct them promptly may result in enforcement action without further notice, such as seizure and/or injunction. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of William W. Knipe, Compliance Officer, at the address noted above.

Sincerely,


Diana J. Kolaitis
District Director

cc: PENNSYLVANIA STATE DEPARTMENT OF AGRICULTURE
Bureau of Foods and Chemistry
2301 North Cameron Street
Harrisburg, PA 17120-9408
Attn: Division of Food Control
Leroy C. Corbin, Jr., Director